REMARKS

I. The Outstanding Rejections

The Examiner rejected claims 15-21, 23-24, and 26-30 under 35 USC §112, first paragraph, as assertedly lacking written descriptive support in the specification.

Applicants respectfully request reconsideration of the rejection in light of the remarks set forth herein.

II. Support for Amendments

Support for the amendment to claim 1 is found, for example, at page 14, first and second full paragraphs, which describes CD40-binding polypeptides contemplated by the invention, including CD154, CD154 extracellular domains, anti-CD40 scFv, and single antibody variable regions that bind CD40. Page 15 describes additional CD154 fragments contemplated. The amendment adds no new matter.

III. Patentability

A. The Rejection of Claims 15-21, 23-24, and 26-30 Under 35 U.S.C. §112, First Paragraph, May Properly Be Withdrawn

The Examiner asserted the specification lacks a written description of the claimed genus of "CD40-binding polypeptides." The Examiner states "that a lack of adequate written description issue also arises if the knowledge and level of skill in the art would not permit one skilled in the art to immediately envisage that product claimed from the disclosed process." See the Action, page 2. The Examiner cites to In re Rochester, which states that while the claimed subject matter of a patent need not be described *in haec verba* in the specification to satisfy the written description requirement, nevertheless, it is also true that the requirement must still be met

in some way so as to describe the claimed invention so that one skilled in the art can recognize what is claimed. In re Rochester 358 F3d 916 (Fed. Cir. 2004). In the Action, however, the Examiner states that Applicant has enabled such CD40-binding polypeptide as CD154 and scFv (Action, page 4, line 1).

Claim 15 as amended recites to CD40-binding polypeptides such as CD154, extracellular domains of CD154 or portions thereof, and anti-CD40 scFv. These CD40-binding polypeptides are described in the specification at, for example, page 14, first and second full paragraphs, which describes CD40-binding polypeptides contemplated by the invention, including CD154, CD154 extracellular domains, anti-CD40 scFv, and single antibody variable regions that bind CD40. Page 15 describes additional CD154 fragments contemplated.

In re Rochester related to a method for inhibiting a particular activity without the patent specification providing any compound that could fulfill the method of the invention. This is not the case in the present situation. Here, Applicants have claimed an antigenic peptide comprising an antigenic component and a CD40-binding polypeptide selected from a specific group of CD40-binding polypeptides.

Moreover, what is conventional or well known to one of ordinary skill in the art need not be disclosed in detail. MPEP 2163 citing Hybridtech v Monoclonal Antibodies, Inc., 802 F2d 1367, 231 USPQ 81 (Fed Cir. 1986). As stated above, several CD40 binding polypeptides are identified in the specification, and others are well known in the art (see below). A worker of ordinary skill would readily understand what is meant by the term "CD40-binding polypeptide," would recognize how to identify any CD40-binding polypeptide not specifically identified in the specification, and would understand that the inventors were in possession of CD40-binding polypeptides.

For example, Pype et al (*J Biol. Chem.* 275:18586-93, 2000, included herewith in Exhibit A), used the CD40 protein to identify "a novel intracellular CD40-binding protein termed TRAF." Pype et al. use the CD40 molecule to identify additional proteins that bind to the CD40 protein, and use the term "CD40-binding protein" to refer to any protein that binds to CD40; Cheng et al. (*Science* 267:1494-8, 1995, abstract included in Exhibit A) use a yeast two hybrid screen to identify another CD40-binding protein CRAF1. These citations demonstrate that one of ordinary skill understands what is meant by a "CD40-binding protein" and that identifying such a protein is routine in the art. Thus, the term "CD40-binding protein" is well-known to one of ordinary skill in the art and need not be exhaustively described in the application.

Furthermore, studies of CD40-binding proteins, such as CD154, have taught those of ordinary skill which amino acid residues are important to CD154-CD40 interaction. See Bajorath, et al., *Biochemistry* 34:1833-44, 1995 (included herewith in Exhibit A). Thus, determining which amino acids within the CD40-binding proteins are important to CD40 binding is routine in the art.

It is understood in the art that while species within the class of CD40-binding polypeptides may not have a strong structural relationship, there is clearly a functional relationship. The Examiner points out that structure/function relationship is only one of many factors to consider, along with functional characteristics, and level of skill in the art, to provide evidence of possession of a genus (see the Action, page 3). As noted above, there is a high level of skill in the art such that a worker of ordinary skill understands and recognizes what is meant by a CD40-binding polypeptide, a term based on the functional characteristic of binding to CD40, and can readily envision and isolate molecules that bind to CD40.

The Examiner further introduces a requirement for the claimed CD40-binding polypeptide which is not in the claim, stating that the "said polypeptide bust [sic] not only be capable of binding to CD40, but they must also facilitate the activation of lymphocytes after fusion protein binding." The Examiner improperly assumes that the CD40-binding protein must bind CD40 and activate the receptor in an asserted manner to induce lymphocyte activation (see the Action, page 3). However, the specification describes that the target binding domain of the invention, in the present case a CD40-binding protein, can bind to the target receptor and activate the cells through receptor-mediated internalization of the antigen into the endocytic compartment of cells expressing the receptor which enhances the presentation of antigenic peptides by MHC class II molecules (page 12, last paragraph), and thereby enhances the immune response to the antigen. Thus, the minimal activity needed by the CD40-binding protein claimed herein is simply binding to CD40.

Applicants' disclosure of representative CD40-binding polypeptides (e.g., antibodies, antibody fragments, CD154 peptides), coupled with the general knowledge and high-level of skill in the art, demonstrates that a person of ordinary skill would readily understand that Applicants were in possession of the claimed compounds.

III. Conclusion

No fees are believed due in connection with this paper. If any fees are deemed necessary, the Commissioner is authorized to deduct any such fees from Marshall, Gerstein and Borun LLP account 13-2855.

Applicants submit that the application is now in condition for allowance and respectfully request notice of the same.

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Respectfully submitted,

By 

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